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10/037,036

10/25/2001

Jonathan S. Stinson

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VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

06/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/037,036 | Applicant(s) STINSON, JONATHAN S. | |
| | Examiner Victor X. Nguyen | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 15-24 and 26-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 15-24 and 26-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Remarks filed 11/13/2007, with respect to claims 1-11,15-24 and 26-32 are acknowledged. However, upon further consideration, a new ground(s) of rejection is made in view of Healy and Penny, III et al. Rejections based on the cited reference(s) follows.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,15,17 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Stinson (6,719,934).

Stinson discloses in figs 7-10 and 14, col.5, lines 27-41, col. 7, lines 40-67 and col. 8, lines 1-22, a process for forming a stent having the limitations of the above listed claims, including: the process comprises the step of forming a tubular stent of the polymer material; the stent radially expanding to produce an expanded diameter stent, and at least one time repeating of steps a-b are all performed prior to deployment of the stent in a body, but Healy is silent regarding the step of annealing the expanded diameter stent or tubular article to shrink its diameter to a reduced diameter.

Stinson further discloses annealing the expanded diameter stent to shrink its diameter to a reduced diameter (see col.25, lines 58-67, col. 26, lines 1-9).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11,15-24,26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Healy et al (5,670,161) in view of Penny III et al (4,816,029).

Healy discloses in fig 5, a process for forming a stent having the limitations of claims 1-23, including: the process comprises the step of forming a tubular stent of the polymer material (see col.9, lines 22-46); the stent radially expanding to produce an expanded diameter stent (see col. 3, lines 9-45), and at least one time repeating of steps a-b are all performed prior to deployment of the stent in a body (see col. 7, lines 50-67), but Healy is silent regarding the step of annealing the expanded diameter stent or tubular article to shrink its diameter to a reduced diameter.

Penny teaches annealing the expanded diameter stent to shrink its diameter to a reduced diameter (see col.4, lines 42-57).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Healy by constructing an annealing the expanded diameter stent to shrink its diameter to a reduced diameter as taught by Penny in order to produce a satisfactory result for an optimal shape of the stent. Regarding claims 3 and 23, Healy discloses the stent is formed by molding or etching the polymer material (see col.9, lines17-21).

Regarding claims 4-5,30,32 Healy discloses the polymer material is thermoplastic or biodegradable (see col.3, lines 31-34).

Regarding claims 6-7 and 19, Healy discloses the polymer material is selected from the group consisting of PLA (poly(alpha-hydroxy acid) which is selected from the group consisting of PLA (polyglycolide) (see col.10, lines 35-49).

Regarding claims 8-9,31 Healy discloses the process has a temperature that is below the glass transition temperature of the polymer material; and wherein the step b) performs at room temperature (see col.3, lines38-45, lines 54-59 and col.4, lines 57-65).

Regarding claims 10-11, Healy discloses the process has a temperature that is above the glass transition temperature of the polymer material; and wherein the step c) performs at a temperature about 130 degree Celsius (see col.10, lines 1-9).

Regarding claims 16-20 ,22-24,27 and 28 Healy discloses a medical device adapted for body lumen navigation (see col. 3, lines 31-60) and a pattern of perforation is seen an a tube wall (see col. 4, lines 36-50).

Response to Arguments

4. Applicant's arguments filed 11/13/2007 have been considered but they are not persuasive.

In response to applicant's argument that Healy reference does not teach a process which involves radial expansion prior to stent delivery. In fact, Healy teaches a stent radially expands to produce an expanded diameter stent (see col. 3, lines 9-45), and the steps a, b are inherently performed prior to deployment of the stent in a body (see col. 7, lines 50-67). Applicant's argument with regard to that Healy's process is not performed at a temperature below the glass

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transition temperature of the polymer material or is performed at room temperature. It is noted again that the phrase a temperature below the glass transition temperature is relatively a broad term which applicant has not positively recited what is a temperature below the glass transition temperature. In fact, Healy teaches “to a point *near* the glass-transition temperature of the copolymer, permitting the stent to enter a rubbery phase that takes advantage of a lower elastic modulus”. This passage can be interpreted broadly that the temperature can be below the glass transition temperature of the polymer material. There is nothing claimed which prohibits this interpretation of the prior art. Finally, applicant’s argument regard to the step of annealing an expanded diameter stent or tubular article to shrink its diameter to a reduced diameter which is still nonpersuasive in light of Penny. Penny teaches annealing the expanded diameter stent to shrink its diameter to a reduced diameter (see col.4, lines 42-57).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Healy by constructing an annealing the expanded diameter stent to shrink its diameter to a reduced diameter as taught by Penny in order to produce a satisfactory result for an optimal shape of the stent. Accordingly, the above noted reference is still considered to read on the claimed limitations of the claimed noted.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ho Jackie can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victor X Nguyen
Examiner
Art Unit 3734

VN
/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773